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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,390	12/12/2001	David Botstein	39780-2830.053 US	9959

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EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 11/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/015,390	BAKER ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33,38-40 and 44-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33,38-40 and 44-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant has identified support for the claim in Application 60/162,506, filed October 29, 1999, in which the utility is first asserted. Because the current claims have a utility rejection, and utility is required to obtain priority, no priority is granted to this application. As MPEP 2163 notes "If the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description, or in the case of a claim for priority under 35 U.S.C. 119, 120, or 365(c), the claim for priority must be denied.

However, assuming arguendo that utility was granted, it is clear that no priority would be given to Application 60/100,661, where no utility for the nucleic acid is provided.

Priority

2. In view of the papers filed October 18, 2004, the inventorship in this nonprovisional application has been changed by the deletion of Kevin P. Baker, Luc Desnoyers, Dan L. Eaton, Napoleone Ferrara, Sherman Fong, Wei-Qiang Gao, J. Christopher Grimaldi, Kenneth J. Hillan, James Pan, Nicholas F. Paoni, Victoria Smith, Timothy A. Stewart, Daniel Tumas, P. Mickey Williams.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Claim Rejections - 35 USC § 112 – Scope of Enablement

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 48-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific Pro1269 sequence of SEQ ID NO: 215, does not reasonably provide enablement for anything which encodes SEQ ID NO: 216, which hybridizes to SEQ ID NO: 215 or which shares some percent identity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in In re Wands, 8 USPQ2d 1400 (CA FC 1988). Wands states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

<u>The nature of the invention and breadth of the claims</u>

The claims are drawn, at their broadest, to a nucleic acid which constitutes only 20 nucleotides that hybridize to SEQ ID NO: 215. The invention is in a class of

invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since there is significant variability in the activity of polypeptides. It would require significant study to identify the actual function of the PRO1269 protein, and identifying a use for this protein would be an inventive, unpredictable and difficult undertaking in itself. With regard to the use of other nucleic acids, it is entirely unpredictable what function other nucleic acids which hybridize to SEQ ID NO: 215. This would require years of inventive effort to determine the functionality of SEQ ID NO: 215, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

The unpredictability of the art and the state of the prior art

The art is extremely unpredictable with regard to protein function in the absence of reliable information regarding the protein activity. Even very similar proteins, as shown by homology, may have very different functions (see Rost et al (J. Mol. Biol. (2002) 318(2):595-608). In the current case, where no specific information is known regarding the function of the protein in actual biological organisms, it is entirely unpredictable what function and activity will be found for this protein. The prior art does not resolve this ambiguity, since no prior art activity is identified for the protein.

Further, the art supports the conclusion that many genes are irrelevant in gene microarray assays. As Li et al (J. Theoretical Biology (2002) 219:513-551) note "The presence of this power law function prevents an intrinsic cutoff point between "important" genes and "irrelevant" genes (see abstract)." Li continues in the text to note that "In a typical microarray experiment, however, the problem is not that one does not put enough genes on a chip, but rather having too many genes (see page 539, column 1)." This concept that genes whose expression does not change is irrelevant is not limited to Li. Ding et al (Bioinformatics (2003) 19(10):1259-66) notes "A two-way ordering of gene expression data can force irrelevant genes toward the middle in the ordering and can thus be discarded (See abstract)." So Ding expressly indicates that genes without change in expression profiling (and Ding's preferred embodiment is cancer genes) should be discarded. Ding notes at page 1259 that in a selection from thousands of genes, 50 are sufficient. Similarly, Sawiris et al (Cancer Research (2002) 62:2923-2928) notes "One of the advantages of specialized arrays is that they do not include irrelevant genes that may contribute to noise during data analysis (see page 2923, column 2)." Thus, the overwhelming state of the art supports the position that many genes are irrelevant, that genes whose expression does not change are noise, and that these irrelevant genes are so insignificant that ideally they are not placed on the arrays or used at all. Therefore, while enablement is conceded for the specific SEQ ID NO: 216, there is no similar expectation of enablement of anything which hybridizes to SEQ ID NO: 215 since such a sequence may represent an entirely different gene with entirely different uses.

Working Examples

The specification has one working example in which the nucleic acid may be overexpressed in some tumor samples/

Guidance in the Specification.

The specification, while showing that PRO 1269 could be generically used in a variety of ways, provides no guidance on the actual use or relevance of PRO 1269. The reference to the related bacterial protein, granulocyte A peptide family, fails to provide any utility since there is no evidence that PRO 1269 shares any functional relationship with this protein.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the presence of a working example which does not address the issue of the efficacy of the control and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Claim Rejections - 35 USC § 112 – Written Description

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 48-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number'' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

All of the current claims encompass a genus of nucleic acids which are different from those disclosed in the specification, since the claims are not limited to any particular SEQ ID NO, but encompass "hybridization" language without any correlative function as required by the utility guidelines.

Most significantly, the genus includes variants for which no written description is provided in the specification. This large genus is represented in the specification by only the particularly named SEQ ID No 215. Thus, applicant has express possession of only one particular nucleic acid sequence in a genus which comprises hundreds of

millions of different possibilities. Here, no common element or attributes of the sequences are disclosed, not even the presence of certain domains.

There is no showing or evidence which links structural limitations or requirements to any particular functional limitations. Further, these claims encompass alternately spliced versions of the nucleic acids, allelic variants including insertions and mutations, nucleic acids which encode inactive precursor proteins which have a removable amino terminal end, and only specific nucleic and amino acid sequences have been provided. No written description of alleles, of upstream or downstream regions containing additional sequence, or of alternative splice variants has been provided in the specification.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

> "A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

In the current situation, the definition of the nucleic acids as hybridizing to SEQ ID NO: 215 lacks any specific structure, since it lacks the correlation between structure and function that is at the heart of the caselaw and of the written description guidelines.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

The current situation is a definition of the compound without identifying the structure function relationship of the compound, so that the compound is claimed solely its nucleic acid sequence which hybridizes to SEQ ID NO: 215 without any correlative function to delimit the structure.

In the instant application, certain specific SEQ ID NOs are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly disclosed which comprise SEQ ID NO 215. Therefore, the claims fail to meet the

written description requirement by encompassing sequences which are not described in the specification.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 33, 38-40 and 44-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Young et al (U.S. 6,444,790).

Young teaches a nucleic acid with 100% nucleic acid sequence identity to SEQ ID NO: 215 as shown in the attached alignment.

This meets the claim limitations of claims 33-34, 38-40 and 48-54.

With regard to claims 44-47, Young expressly teaches expression of the sequence in vectors and host cells including yeast and E. coli (see column 16, line 55 to column 17, line 67).

9. Claims 33 and 48-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Kang et al (Proc. Natl. Acad. Sci. (August 1998) 92:10078-10082) as evidenced by Genbank Accession No. AF076483 (August 15, 1998).

Kang teaches a nucleic acid which will hybridize to SEQ ID NO: 215 and which is at least 100 nucleotides (see page 10078, bottom right data deposition, where AFO76483 is indicated as deposited). Further, Kang's sequence comprises the full length coding sequence "from within" SEQ ID NO: 215. Kang's sequence alignment with SEQ ID NO: 215 is shown below. So while Kang's sequence is not identical to that of SEQ ID NO: 215, it will hybridize under any stringency conditions whatsoever and is certainly more than 100 nucleotides in length.

```
Score = 1298 bits (655), Expect = 0.0
 Identities = 668/671 (99%), Gaps = 1/671 (0%)
 Strand = Plus / Plus

Query: 1   tcccggaccctgccgccctgccactatgtcccgccgctctatgctgcttgcctgggctct 60
           |||||| ||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 20  tcccggcccctgccgccctgccactatgtcccgccgctctatgctgcttgcctgggctct 79

Query: 61  ccccagcctccttcgactcggagcggctcaggagacagaagacccggcctgctgcagccc 120
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 80  tcccagcctccttcgactcggagcggctcaggagacagaagacccggcctgctgcagccc 139

Query: 121 catagtgccccggaacgagtggaaggccctggcatcagagtgcgcccagcacctgagcct 180
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 140 catagtgccccggaacgagtggaaggccctggcatcagagtgcgcccagcacctgagcct 199

Query: 181 gcccttacgctatgtggtggtatcgcacacggcgggcagcagctgcaacacccccgcctc 240
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 200 gcccttacgctatgtggtggtatcgcacacggcgggcagcagctgcaacacccccgcctc 259

Query: 241 gtgccagcagcaggcccggaatgtgcagcactaccacatgaagaca-tgggctggtgcga 299
           |||||||||||||||||||||||||||||||||||||||||||| ||||||||||||
Sbjct: 260 gtgccagcagcaggcccggaatgtgcagcactaccacatgaagacactgggctggtgcga 319

Query: 300 cgtgggctacaacttcctgattggagaagacgggctcgtatacgagggccgtggctggaa 359
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 320 cgtgggctacaacttcctgattggagaagacgggctcgtatacgagggccgtggctggaa 379

Query: 360 cttcacgggtgcccactcaggtcacttatggaaccccatgtccattggcatcagcttcat 419
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Sbjct: 380 cttcacgggtgcccactcaggtcacttatggaaccccatgtccattggcatcagcttcat 439


Query: 420 gggcaactacatggatcgggtgcccacaccccaggccatccgggcagcccagggtctact 479
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 440 gggcaactacatggatcgggtgcccacaccccaggccatccgggcagcccagggtctact 499


Query: 480 ggcctgcggtgtggctcagggagccctgaggtccaactatgtgctcaaaggacaccggga 539
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 500 ggcctgcggtgtggctcagggagccctgaggtccaactatgtgctcaaaggacaccggga 559


Query: 540 tgtgcagcgtacactctctccaggcaaccagctctaccacctcatccagaattggccaca 599
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 560 tgtgcagcgtacactctctccaggcaaccagctctaccacctcatccagaattggccaca 619


Query: 600 ctaccgctccccctgaggccctgctgatccgcaccccattcctcccctcccatggccaaa 659
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 620 ctaccgctccccctgaggccctgctgatccgcaccccattcctcccctcccatggccaaa 679


Query: 660 aaccccactgt 670
           ||||||||||||
Sbjct: 680 aaccccactgt 690
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Response to 1.131 Declaration

10. The Declaration filed on October 18, 2004 under 37 CFR 1.131 has been considered but is ineffective to overcome the Young reference.

The Declaration is not persuasive for several reasons. First, it is unsigned. Second, even if signed, no utility is provided.

Response to Arguments

11. Applicant's arguments filed October 18, 2004 have been fully considered but they are not persuasive.

The Applicant does not dispute the identity of the reference with the invention of the claims. Applicant cites the Stempel doctrine to overcome the rejection. Applicant is advised to reread the quotation regarding Stempel, which states in relevant part "unless

the reference also teaches how to use the compound it describes (see page 20 of response)." This is precisely that situation. It is undisputed, and actually admitted by Applicant, that their provisional appication 60/100,661 does not provide any utility for the claimed sequence.

Young is a reference that also teaches how to use the compound it describes. However, Applicant argues that Young does not provide utility. This is easily rebutted in two ways. The Young patent is literally identical to the provisional from which it depends (60/113,809). The Young patent provides identical utilities for the claimed SEQ ID NO: 4 and for the sequence at issue, SEQ ID NO: 6. Since issued patents are PRESUMED useful and enabled, and no evidence overcoming that presumption has been presented, Young is presumptively enabled for SEQ ID NO: 6 simply based on the fact that the patent issued.

However, the case for utility for SEQ ID NO: 6 is much better than that. Young specifically provides utilities for SEQ ID NO: 6, which is the sequence that anticipates the current claims. Young teaches specific diagnosis of specific disorders including wound healing at column 6, lines 48-67. This is a specific and substantial utility, unlike those presented in the current application. Applicant therefore is incorrect in stating that the specification is devoid of experimental evidence supporting utility. The specification expressly states this diagnostic ability and the differential expression of the protein during wound healing. Diagnosing problems in wound healing is clearly a credible, specific and substantial utility.

Therefore, based upon the Stempel doctrine, the rejection is maintained.

With regard to the enablement and written description rejections, the "function" of detecting cancer in the claims using the "hybridization" language does not comply with the function indicated as satisfactory by the Guidelines. In Example 9, a specific enzymatic function is associated with the "stringent hybridization" language. The function in the guidelines is enzyme activity, selected for use in the guidelines because that function limits the genus of possible nucleic acids. The function of detecting cancer does not so limit the genus, because there is no necessary expectation that different sequences will share common core structures in cancerous cells, unlike that expectation for enzymes like ligase.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman
Primary Examiner
Art Unit 1637
11/4/09